DEVELOPMENT OF COSTS FOR THE PROCESS FOR THE REVIEW OF MEDICAL DEVICE APPLICATIONS

GENERAL METHODOLOGY

The costs associated with the process for the review of medical device applications are based on obligations recorded within FDA's CDRH, CBER, ORA, and HQ. These organizations correspond to the cost categories presented as follows:

Cost Category	FDA Organization
Costs for the Review of PMAs, PDPs, PMRs, Modular PMAs, Supplements, and 510(k)s	CDRH
Costs for the Review of BLAs, PMAs, Supplements, and 510(k)s	CBER
Costs for Field Inspection and Investigation	ORA
Costs for Agency General and Administration	HQ

The costs for each component, shown in Table 7 on page 9, were derived using time-reporting systems in CDRH, CBER, and ORA, and were calculated for HQ as described in more detail in this Appendix. Using the definitions of costs and activities included in the process for the review of medical device applications in MDUFA, as explained in the discussion in Appendix D, the cost categories within each organization listed above were identified as parts of the medical device review process.

CENTER COSTS

Costs of the medical device review program are tracked for each organizational component in CDRH and CBER, usually at the division level. Most FDA components involved in the process perform a mixture of activities – some within the definition of the process for the review of device applications, and some not. FDA groups its organizational components into three categories:

- direct review and laboratory;
- indirect review and support; and
- Center-wide costs.

The allocation of costs for each category is discussed below.

Direct Review and Laboratory

Employees in all components of CDRH and CBER, other than those noted below as Center indirect review and support components, reported their time in activities that could be used to differentiate between time spent on the process for the review of device applications and all other time.

Both CDRH and CBER have existing time-reporting systems in place. These time-reporting systems were modified after the enactment of MDUFA, so that time could be reported in categories that could be separated into allowable and excluded activities with respect to the process for the review of device applications, as defined in MDUFA and as further defined in Appendix D. This process is further explained below.

Ten years prior to the enactment of MDUFA, CDRH's time-reporting system had been used to gather information about employee time for a two-week period one or two times each year. After the definitions of allowable and excluded costs for the process for the review of device applications under MDUFA were further refined, as presented in Appendix D, the time-reporting categories in the CDRH time-reporting system were modified so that all data captured would fit into either allowable or excluded costs. These modifications to the system were completed in mid-June 2003.

Once these modifications were completed, all CDRH employees other than management and administrative personnel reported all of the time they worked against these revised categories for a period of eight consecutive weeks, from June 29 through August 23, 2003. Whether time categories were counted as allowable or excluded was not apparent to employees as they reported their time.

FDA Centers are very payroll-intensive. About 53 percent of all FDA funds go to pay for employee salary and benefits. Almost all other costs directly support these employees. Given this payroll-intense cost structure, the percent of time reported as having been expended on allowable device review process activities for each cost-center (usually an organization component at the Division level) is then applied to all costs incurred for that cost-center for the entire fiscal year.

Further, since these percentages of allowable costs had never been collected for earlier periods, the percentages of allowable costs reported in this eight-week period were likewise applied to each cost-center's direct costs (obligations) incurred in FY 2002, to get the baseline FY 2002 device review process cost data required under MDUFA.

For FY 2004 and FY 2005, all CDRH employees, other than management and administrative personnel, reported all of the time they worked against these revised categories for one two-week period during each quarter of the fiscal year. The results from the eight weeks of time reporting data were then averaged and extrapolated to the entire year. This served as the basis for measuring CDRH costs for the device review process for direct review and laboratory components, and the same pattern has been followed in subsequent years. In addition, further

modifications were made in FY 2005 to be able to break out time for various specific types of application review.

In FY 2006, CDRH modified its time reporting categories to better account for effort on training, guidance document and standards development, and outreach initiatives. Prior to FY 2006, most of these areas were considered part of the MDUFA process. These changes allowed CDRH to better distinguish between premarket and postmarket efforts.

In FY 2007, CDRH continued to make minor refinements to the CDRH automated time reporting system. Based on requests from staff, CDRH added several reporting activities to improve reporting accuracy. New activity codes were created to further define premarket review activities, reflect organizational transformation initiatives, and differentiate between user fee and appropriated MQSA program management activity. CDRH also added numerous "sub-activities" to the existing activities in all program areas so that staff could easily identify and report their time in the appropriate categories. Further refinements were made in FY 2008 to accommodate changes under MDUFA II (e.g., added time categories for 30-day notices, PMA supplements, and PMA annual reports). These enhancements did not have a significant effect on FDA's MDUFA process calculations.

A similar procedure is used in CBER to measure the direct review and laboratory components costs for the device review process. CBER was able to use the time-reporting system it has had in place for over 10 years prior to the enactment of MDUFA, and which was validated by studies done prior to and after the Prescription Drug User Fee Act (PDUFA) was enacted in 1992. That system collects time reports from all employees other than management and administrative support personnel for a two-week period during each quarter of the fiscal year.

CBER's existing time-reporting system was also modified to ensure that activities against which time was reported could be clearly divided into those activities that were either allowable or excluded in the MDUFA-defined process for device application review. The results from each two-week period of time reported are extrapolated for the quarter being reported. The extrapolated results for each quarter are averaged to estimate the full year costs.

CBER's process for determining allowable and excluded costs for MDUFA direct review and laboratory costs is identical to how CBER determines costs for the process for the review of human drug applications. This process was validated by Arthur Andersen, LLC under PDUFA for 1992 and 1993.

Indirect Review and Support

Indirect review and support components provide the infrastructure for the review process. In CDRH, these are the Office of the Center Director and the Office of Management and Operations. In CBER, these components include the Office of the Center Director, Office of Management, and the Office of Communications, Outreach, and Development.

In both CDRH and CBER, the allowable costs for these indirect review and support components

were determined by multiplying the average percent of allowable costs for all direct review and laboratory components by the total costs of each of these indirect review and support components.

Center-Wide Costs

A number of Center-wide and agency-wide expenses are paid from the central accounts of the Center or of FDA rather than from funds allocated to a specific Center or division or office within the Center. These costs include rent for facilities that house CDRH and CBER staff, telecommunications and utility costs, some computer equipment and support costs, and costs of the Office of Shared Services, which supports all FDA programs and activities. For these Center- and agency-wide costs, a percentage of them are chargeable to the process for the review of medical device applications. That percentage is either a specific amount that is supported by independent documentation or is the amount of time reported for allowable activities (direct and indirect) in the Center, as a percentage of total time reported for all Center direct and indirect activities.

In support of the President's Management Agenda and the Secretary's Goal of "one-HHS," FDA was requested to consolidate its administrative functions (including facilities, procurement, finance, EEO, and IT services) to carry out more efficient realignment of the resources, which would provide high quality administrative services from a single organization. FDA created an Office of Shared Services in FY 2004. It combined the support responsibilities and resources previously located both in the Centers and in HQ, and ensured effective and efficient services in a competitive market environment.

Prior to FY 2004, many of the Office of Shared Services FTE employees and resources were performed in CDRH, CBER, ORA, and HQ. In FY 2012, resources expended by the Office of Shared Services in supporting the medical device review process are reported as if they were incurred in CDRH, CBER, ORA, or HQ for comparability to the FY 2003 base year.

FIELD INSPECTION AND INVESTIGATION COSTS

ORA incurs all field inspection and investigation costs. ORA costs are incurred in both district offices (the "field") and headquarters support offices and are tracked in Field Accomplishments and Compliance Tracking System (FACTS). FACTS is a time and activity tracking system which captures time in a variety of categories, including pre-approval inspections of manufacturing facilities, investigations of clinical studies, and analytical testing of samples--which are included in the process for the review of medical device applications.

Total direct hours reported in FACTS are used to calculate the total number of staff-years required by ORA to perform activities in the process for the review of device applications as defined in MDUFA. In addition to the direct time, an allocation of support time is also included to represent the work done by the ORA administrative and management personnel. The agency then applies the total number of staff years devoted to the process for the review of device applications to the average salary cost in ORA to arrive at the ORA salary costs for the process for the review of device applications as defined in MDUFA. The final step is to allocate ORA obligations for operations and

rent to the device review process based upon the ratio of user fee related staff years to total ORA staff years.

Table 14 summarizes the calculation of ORA costs for the process for the review of medical device applications for FY 2011 and FY 2012, including costs paid from appropriations and costs paid from fee revenues.

TABLE 14
OFFICE OF REGULATORY AFFAIRS
COSTS OF THE REVIEW PROCESS FOR MEDICAL DEVICE APPLICATIONS
AS OF SEPTEMBER 30, 2012

COST COMPONENT	FY 2011	FY 2012
Staff Years Utilized	68	68
ORA Average Salary and Benefits	$110,499	$114,268
Total Salary and Benefits	$7,513,932	$7,770,224
Operating and Other Costs[1]	$6,950,955	$7,780,356
GRAND TOTAL (salary/benefits and operating/other costs)	**$14,464,887**	**$15,550,580**

[1]Other costs are central, GSA rent, rent-related, and Shared Services costs that are applicable to the process for the review of device applications.

AGENCY GENERAL AND ADMINISTRATIVE COSTS

The agency general and administrative costs include all costs incurred in FDA's HQ that are attributable to the Office of the Commissioner and all other FDA headquarters components that are not Centers or the Office of Regulatory Affairs. For the purpose of these calculations, HQ is considered to be comprised of the following offices:

- Immediate Office of the Commissioner
- Office of the Counselor to the Commissioner
- Office of Legislation
- Office of Policy and Planning
- Office of External Affairs
- Office of the Executive Secretariat
- Office of the Chief Counsel
- Office of Minority Health
- Office of Women's Health
- Office of the Chief Scientist (excluding the National Center for Toxicological Research)
- Office of Operations

- Office of Foods (excluding the Center for Food Safety and Applied Nutrition and the Center for Veterinary Medicine)
- Office of Medical Products and Tobacco (excluding the Center for Drug Evaluation and Research, the Center for Biologics Evaluation and Research, the Center for Devices and Radiological Health, and the Center for Tobacco Products)
- Office of Global Regulatory Operations and Policy (excluding the Office of Regulatory Affairs)

In summary, HQ costs include all of FDA except for the six product-oriented Centers, ORA, and the National Center for Toxicological Research.

The HQ costs applicable to the process for the review of medical device applications were calculated using a method prescribed by the Division of Cost Determination Management, Office of Finance, Office of the Secretary, Department of Health and Human Services. The method uses the percentage derived by dividing total HQ costs by the total FDA salary expenses (excluding benefits) after subtracting the salary expense (excluding benefits) from HQ. That percentage is then multiplied by the sum of salaries (excluding benefits) applicable to the process for the review of medical device applications in CDRH, CBER, and ORA to derive the applicable agency general and administrative costs.

Using this methodology, FDA dedicated $25,921,857 in general and administrative costs to the medical device review process in FY 2012. The costs are total costs obligated from appropriations and user fees. FDA strives to maintain a low overhead cost for the review process of medical device applications. General and administrative costs are approximately 8 percent of FY 2012 total medical device review process costs.